

## REMARKS

Claims 1 and 3-24, as amended, appear in this application for the Examiner's review and consideration. Claims 1 and 14 have been amended to clarify the present invention by reciting that the system and method are used to form in the stratum corneum a plurality of micro-channels having a diameter of about 10 microns to about 100 microns and a depth of about 20 microns to about 300 microns, support for which is found in paragraphs [0024] and [0062] of the published application. Since no new matter is introduced by these changes, the amendment should be entered at this time to reduce the issues for appeal and place the claims in condition for allowance.

Claims 1, 3-7, 9-10, 12-17, 19-20, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0010414 to Coston et al. (referred to hereafter as "Coston") in view of U.S. Patent No. 6,302,874 to Zhang et al. (referred to hereafter as "Zhang").

Coston relates to a method and a device for transporting a molecule through a mammalian barrier membrane of at least one layer of cells through electroporation of the membranes. Coston defines electroporation as ablation of a barrier membrane so as to produce pores in the membrane (see paragraph [0045] of Coston). According to Coston, the pores refer to disruptions of the membrane leading to an increased molecular transport. The pore as disclosed by Coston is not restricted by its size and shape and may be a discrete hole having a diameter of between about 1  $\mu$ m to about 5 mm, or a line having a length up to about 10 cm (paragraph [0045] of Coston). A wide variety of molecules including therapeutic drugs or any material capable of exerting a biological effect on a human body are taught by Coston (see paragraphs [0014], [0061] and [0062] of Coston). Coston teaches various apparatuses for the electroporation methods. One apparatus comprises a housing, a current generator, a current controller, and a treatment electrode for electroporation in a mono-terminal operation (see paragraph [0067] and FIG. 1 of Coston). Another apparatus comprises a housing, an electric current generator, an electric current controller, a treatment electrode for electroporation, and an indifferent electrode (see paragraph [0072] and FIG. 2a of Coston). Yet another electroporation apparatus is a bi-terminal apparatus with two treatment electrodes located very close to, but separated from, each other (see paragraph [0074] and FIG. 2b of Coston). In

summary, the electroporation apparatuses disclosed by Coston comprise treatment electrode(s) which are an integral part of the apparatuses. Coston does not disclose an apparatus which comprises a main unit and an electrode cartridge comprising a plurality of electrodes wherein the main unit is adapted to apply electrical energy between the electrodes to generate channels through which cosmetic agents can be delivered without causing skin damage, as recited and claimed in the present claims as amended. Zhang does not remedy the deficiencies of Coston.

Zhang teaches apparatuses for electroporation so as to create transient aqueous pathways (pores) in lipid bilayers (see col. 2, ll. 65-66; and col. 4, ll. 31-33 of Zhang). A typical apparatus according to Zhang comprises a mini pulse generator in electrical contact with an electrode (see col. 10, ll. 30-34 of Zhang). The electrode according to Zhang can be an insulated or porous meander electrode, which comprises an interweaving array of metal fingers (see col. 10, ll. 45-47; and col. 12, ll. 49-50 of Zhang). Zhang discloses that the various electrodes used in the apparatus are preferably insulated to protect against excess heat or burning, current leakage, shock, and the like (see col. 10, ll. 63-66; and col. 12, ll. 56-58 of Zhang). Moreover, Zhang teaches an electrode that can be backed with an adhesive film that can be peeled off for use (see col. 14, ll. 66-67 of Zhang). Zhang further discloses a "mounting bracket" to which the electrodes can be mounted. Because the electroporation according to Zhang is achieved by pulsed electric fields, specifically electrostatic fields (see Figure 2; col. 4, ll. 51-54; col. 9, ll. 61-63; col. 10, ll. 1-6; col. 10, ll. 14-16 of Zhang), the electrodes of Zhang are preferably insulated. Moreover, as the pores formed by electroporation are small and transient, the delivery of L-ascorbic acid according to Zhang is enhanced by applying an electric pulse having sufficient strength and duration to the composition so as to topically deliver L-ascorbic acid to the region of skin by the electric pulse(s) (see col. 4, ll. 31-42; and col. 7, ll. 10-18 of Zhang). Thus, even if a person of ordinary skill in the art modifies the device of Coston to have an electrode cartridge to contain the plurality of electrodes taught by Zhang in order to enable the electrode to be detachable to allow different electrode types and/or shapes to be used, he would only obtain a device comprising a housing, a current generator, a current controller, and a mounting bracket with insulated or porous meander electrodes attached. Although such a device would be effective for electroporation, i.e., creating transient pores in the lipid bilayer, it would not be effective in creating micro-channels extending from the surface of the skin through the stratum corneum as recited and claimed in the present claims as amended. Furthermore, such a device

would typically require applying electric pulses to the composition to achieve efficient delivery of a cosmetic agent, which is completely different from the system of the present invention wherein the cosmetic agent is delivered to the skin by simple diffusion without the application of electrical energy to the composition (see paragraph [0026] of the published application).

Additionally, the pore disclosed in Coston is not restricted by its size and shape, and it may be a discrete hole having a diameter, for example, of about 1  $\mu\text{m}$  to about 5 mm, or a line having a length up to about 10 cm (see paragraph [0045] of Coston). Therefore, the pore of Coston is not restricted in its size to enable therapeutic drug delivery into the human body to exert a biological effect, or alternatively to enable transporting of a molecule from the human body to the apparatus for diagnostic uses (see paragraphs [0014] and [0019] of Coston). Due to its large dimensions, the pore of Coston causes skin damage and is therefore not desired for cosmetic uses. In contrast, the pores created by electroporation of Zhang are small and transient pathways in the lipid bilayer (see col. 2, ll. 65-66 of Zhang). In order to enable efficient dermatological delivery of L-ascorbic acid, Zhang discloses that the composition is applied prior to or concurrently with electropulsing to dermatologically deliver the L-ascorbic acid into the skin by the electric pulses. Thus, even if the device of Coston is modified to have an electrode cartridge to contain the plurality of electrodes as taught by Zhang, one would only obtain a device capable of generating small and transient pathways in the lipid bilayer, instead of micro-channels of the present invention having the shape of a channel extending from the surface of the skin through the stratum corneum to enable intradermal or transdermal delivery of a cosmetic agent without the application of electrical energy to the composition and without causing skin damage (see paragraphs [0018] and [0048] of the present application). In order to further distinguish the apparatus of the present invention from the device of Coston modified by Zhang, claim 1 has been amended to recite that the diameter of the micro-channels generated by the apparatus of the present invention is of about 10 to about 100 microns and their depth is of about 20 to about 300 microns. Such dimensions of the micro-channels are particularly crucial to practice the present invention as they allow intradermal or transdermal delivery of cosmetic agents into the depth of the micro-channels and not beyond that depth so as to achieve improvement of the appearance of the skin and only of the skin (see paragraphs [0017], [0047], [0065], [0067], and [0177] of the published application).

Also, due to the fact that the device of Coston has a roller body that contains the electrode array (see Fig. 6 and paragraph [0088] of Coston), even if a person of ordinary skill in the art modifies the device taught by Coston to have a detachable electrode cartridge containing a plurality of electrodes, he would not obtain the micro-channels of the present invention having the particular diameter and depth as recited in claims 1 and 14 as amended. Thus, claims 1 and 14 as amended and their dependent claims are patentable over Coston in view of Zhang. Therefore, the rejection over Coston in view of Zhang should be withdrawn.

Claims 8, 11, 18, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coston in view of Zhang, and further in view of U.S. Patent No. 6,477,410 to Henley (referred to hereafter as "Henley").

Henley teaches a self-powered hand-held electrokinetic delivery device for self-administering a medicament by driving the medicament from an applicator into the treatment site (see col. 6, ll. 50-54 of Henley). Although Henley discloses different medicaments including hydroquinone and antibacterial agents to be delivered electrokinetically, Henley does not disclose a device capable of generating micro-channels having a diameter of about 10 to about 100 microns and a depth of about 20 to about 300 microns as recited and claimed in the present claims as amended. Thus, even one of ordinary skill in the art attempts to modify the device of Coston in view of Zhang to deliver hydroquinone or an antibacterial agent taught by Henley, he would not be able to reach the system of the present invention as claimed. Therefore, the rejection over Coston in view of Zhang, and further in view of Henley should be withdrawn.

Accordingly, it is believed that the entire application is in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of this application.

Respectfully submitted,

Date: \_\_\_\_\_

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